

# TEAM 14026: SYSTEM DESIGN REVIEW

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# AGENDA

- Problem Statement
- Customer Needs & Engineering Requirements
- Functional Decomposition
- Process Proposal
- Concept Generation
- Design Drawings
- Concept Selection
- Test Plan
- Risk Analysis
- Benchmarking
- Moving Forward

# PROBLEM STATEMENT

- **Current State**
  - 1<sup>st</sup> generation of a validation system
- **Desired State**
  - Simulate the respiratory system and measure flow, pressure, volume, and oxygen concentration
- **Project Goals/Opportunities**
  - Collect data to evaluate 13027's PEV
- **Constraints**
  - ANSI Z79.7
  - ISO 5469:1967
  - ASTM F1100-90
  - ISO 80601-2-12

# OLD MATRIX

Needs	Priority	Engineering Requirements												
		Air Pressure	Lung Compliance	Resistance of Trachea & Lung	Rate of air intake	PEEP level	Tidal Volume	Inhaler/Exhale Ratio	Maximum lung volume	Flow rate	Minimum Oxygen Concentration	Maximum Carbon Dioxide Concentration	Expense of parts	Weight
Adjustable Lung Compliance	9	X	X					X		X				
Adjustable Trachea and Lung Resistance	3	X		X	X					X				
Measures Respiratory Rate	9				X			X						
Measures that air pressure is always at PEEP level	9	X				X								
Adjustable Tidal Volume Capacity	3	X	X	X	X			X						
Measures Inspiration/Exhalation Ratio	9				X			X						
Measures pressure levels	9	X		X		X	X		X					
Measures max lung volume	9		X				X		X					
Measures flow rates	9			X	X			X		X				
Displays pressure-volume curve	3	X		X	X	X	X		X					
Measures oxygen concentration	9									X				
Measures carbon dioxide concentration	3										X			
Minimizes expenses	3											X	X	
Units of Measure		cm H2O	L/cm H2O	cm H2O/L/sec	breaths/min	PSI	mL	unit less	L	L/sec	ppm	ppm	Dollars	kg

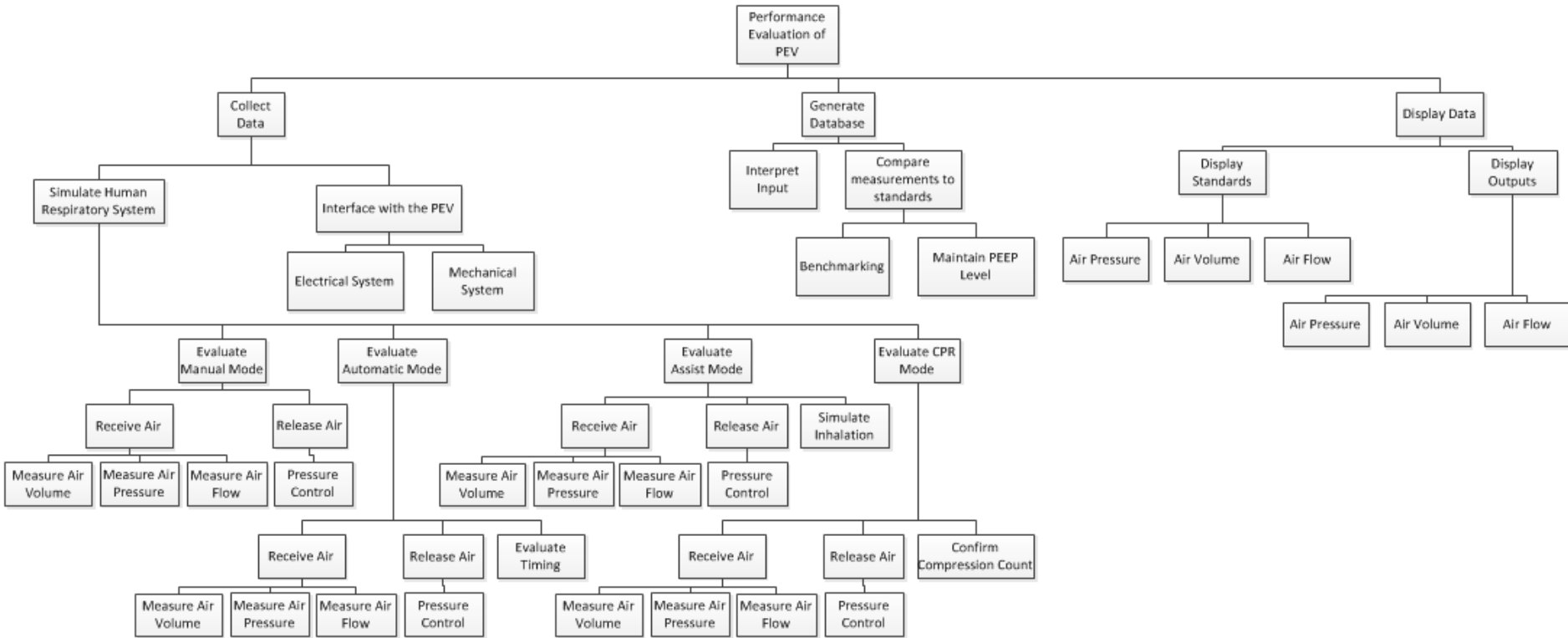
# NEW MATRIX

Needs		Priority		Engineering Requirements																			
				Air Pressure	Lung Compliance	Resistance of Trachea & Lung	Rate of air intake	PEEP level	Tidal Volume	Inhale/Exhale Ratio	Maximum lung volume	Flow rate	Minimum Oxygen Concentration	Maximum Carbon Dioxide Concentration	Expense of parts	Weight	Vibration test	Drop test	Ergonomics of the PEV	EML test of PEV	Performance of PEV system alarms	Suction of connection between human and PEV	Battery life of PEV
Adjustable Lung Compliance	9	X	X				X		X														
Adjustable Trachea and Lung Resistance	3	X		X	X					X									X				
Measures Respiratory Rate	9				X				X														
Measures that air pressure is always at PEEP level	9	X				X													X				
Adjustable Tidal Volume Capacity	3	X	X	X	X		X																
Measures Inspiration/Exhalation Ratio	9				X			X															
Measures pressure levels	9	X		X		X	X			X									X				
Measures max lung volume	9		X				X		X														
Measures flow rates	9			X	X			X		X													
Displays pressure-volume curve	3	X		X	X	X	X		X	X													
Measures oxygen concentration	9										X												
Measures carbon dioxide concentration	3										X												
Minimizes expenses	3											X	X										
Validation of PEV	1	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X
Test Report	1	X	X	X	X	X	X	X	X	X	X	X							X				
Repeatable Test Process	9																						
Validation of 4 PEV Modes	9	X	X	X	X	X	X	X	X	X	X	X							X				
Test at STP	1																						
Validate testing for neonatal to adult	9	X	X	X	X	X	X	X	X	X	X	X							X				
Units of Measure		cm H2O	L/cm H2O	cm H2O/L/sec	breaths/min	PSI	mL	unit less	L	L/sec	ppm	ppm	Dollars	kg	radians/sec	PSI	multiple units	kV/m		kPa	hours		

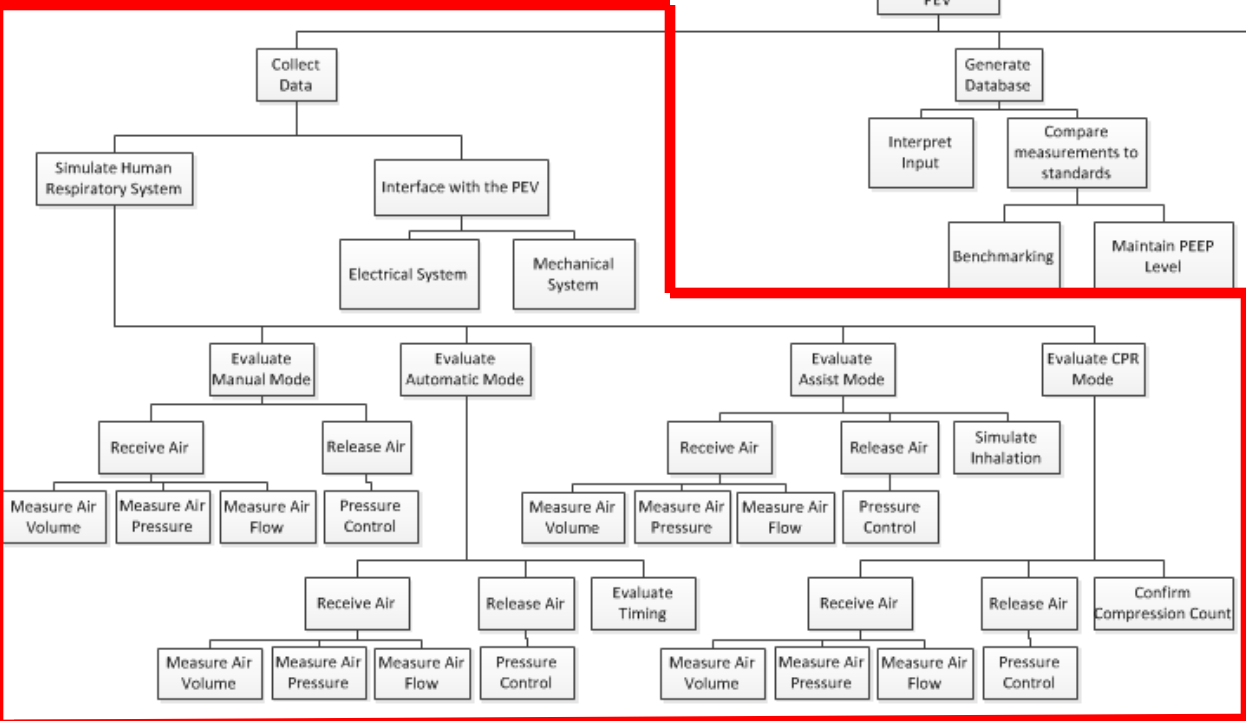
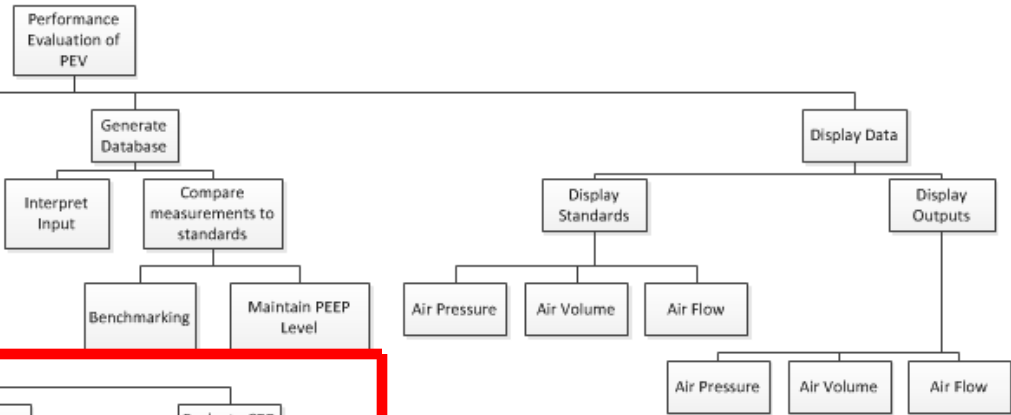
# DEFINING THE SCOPE

Needs		Priority	Engineering Requirements																					
Units of Measure			Air Pressure	Lung Compliance	Resistance of Trachea & Lung	Rate of air intake	PEEP level	Tidal Volume	Inhale/Exhale Ratio	Maximum lung volume	Flow rate	Minimum Oxygen Concentration	Maximum Carbon Dioxide Concentration	Expense of parts	Weight	Vibration test	Drop test	Ergonomics of the PEV	EMI test of PEV	Performance of PEV system alarms	Suction of connection between human and PEV	Battery life of PEV	Clear PEV of pathogens	
	Adjustable Lung Compliance	9	X	X				X		X														
	Adjustable Trachea and Lung Resistance	3	X		X	X					X									X				
	Measures Respiratory Rate	9				X			X															
	Measures that air pressure is always at PEEP level	9	X				X													X				
	Adjustable Tidal Volume Capacity	3	X	X	X	X		X																
	Measures Inspiration/Exhalation Ratio	9				X			X															
	Measures pressure levels	9	X		X		X	X			X									X				
	Measures max lung volume	9		X				X		X														
	Measures flow rates	9			X	X			X		X													
	Displays pressure-volume curve	3	X		X	X	X	X		X	X													
	Measures oxygen concentration	9										X												
	Measures carbon dioxide concentration	3											X											
	Minimizes expenses	3												X	X									
	Validation of PEV	1	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X
	Test Report	1	X	X	X	X	X	X	X	X	X	X	X	X						X				
	Repeatable Test Process	9																						
	Validation of 4 PEV Modes	9	X	X	X	X	X	X	X	X	X	X	X	X						X				
	Test at STP	1																						
	Validate testing for neonatal to adult	9	X	X	X	X	X	X	X	X	X	X	X	X						X				

# FUNCTIONAL DECOMPOSITION

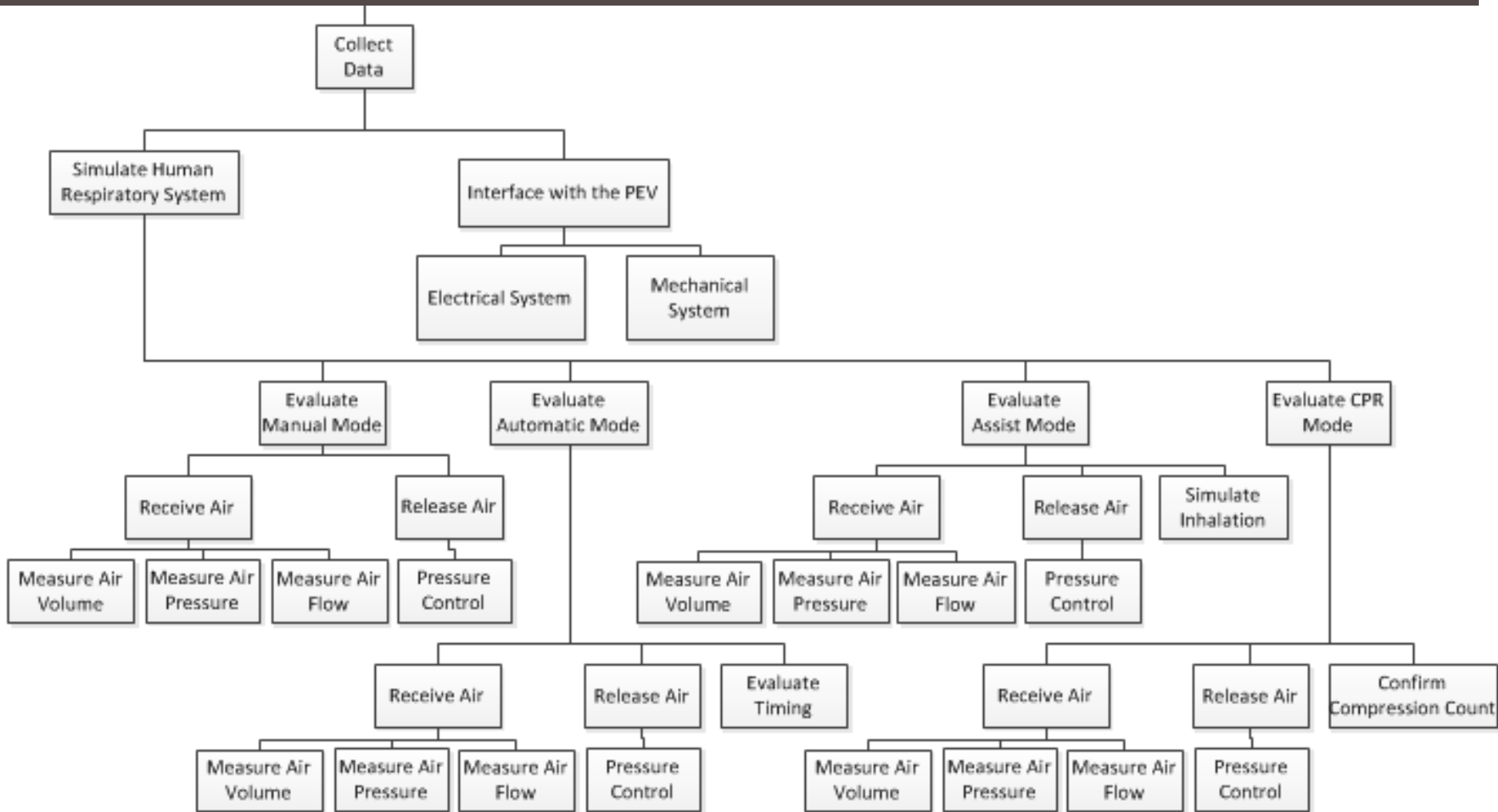


# FUNCTIONAL DECOMPOSITION

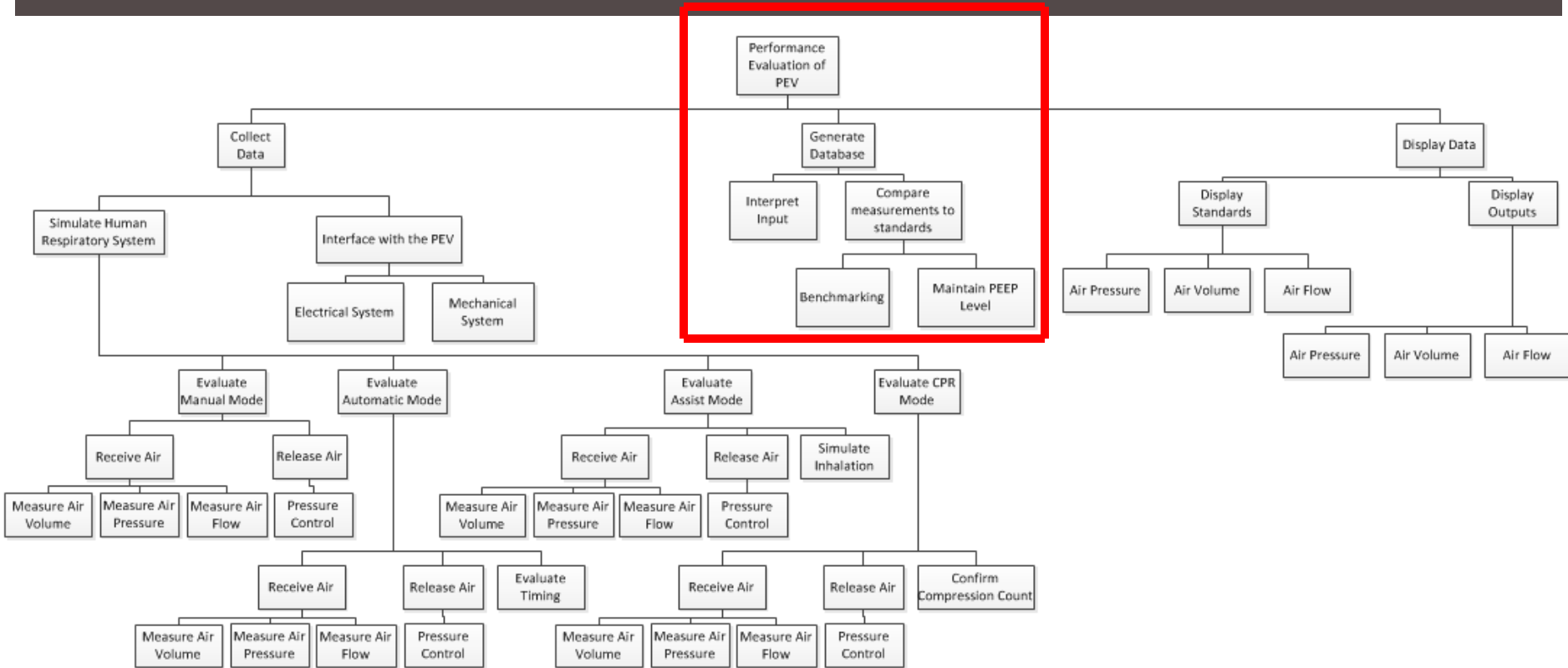




# FUNCTIONAL DECOMPOSITION



# FUNCTIONAL DECOMPOSITION



# FUNCTIONAL DECOMPOSITION

Performance  
Evaluation of  
PEV

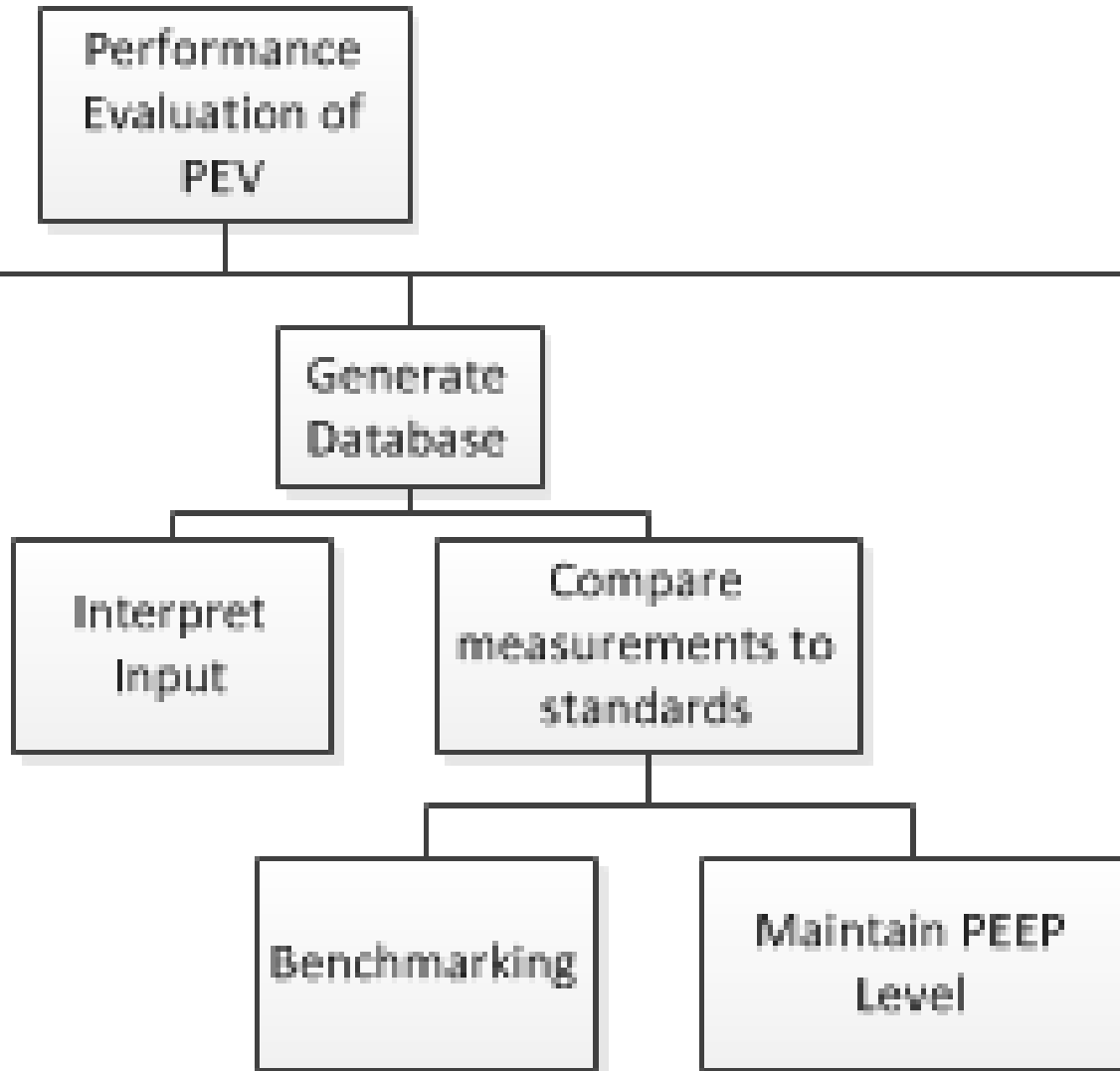
Generate  
Database

Interpret  
Input

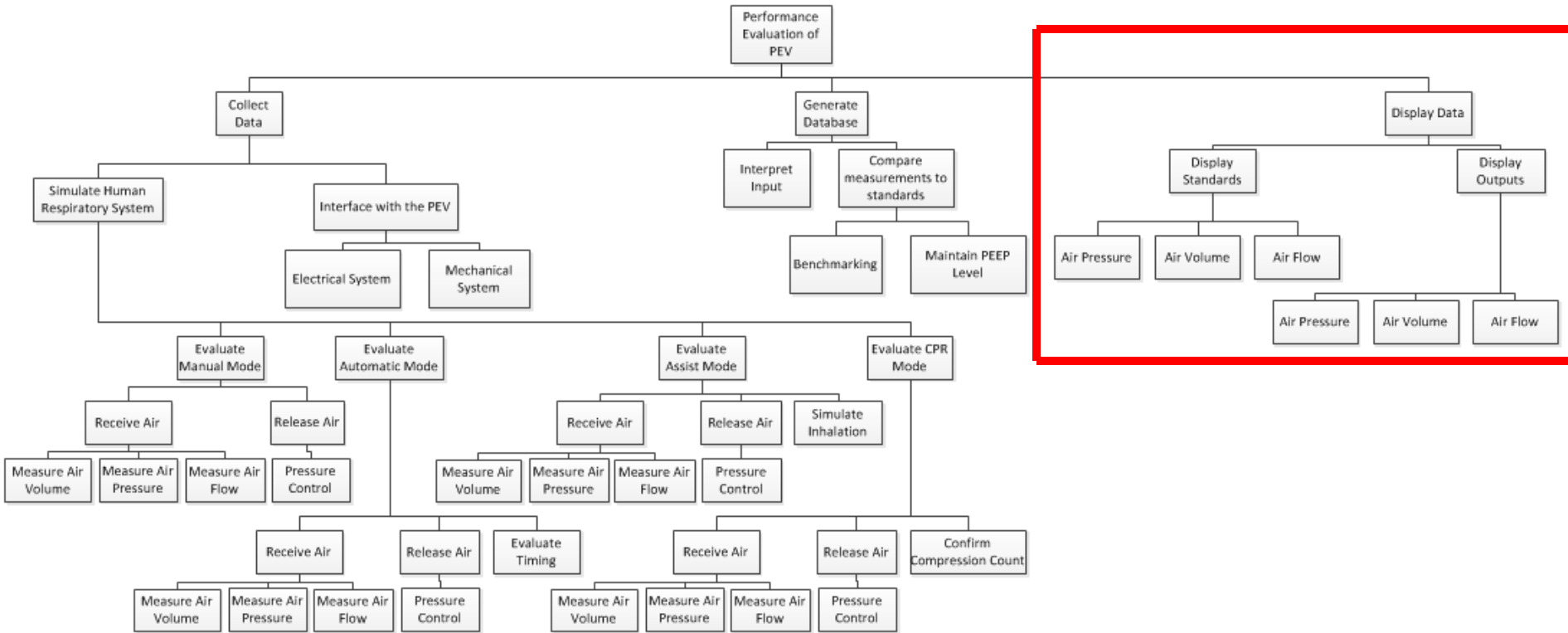
Compare  
measurements to  
standards

Benchmarking

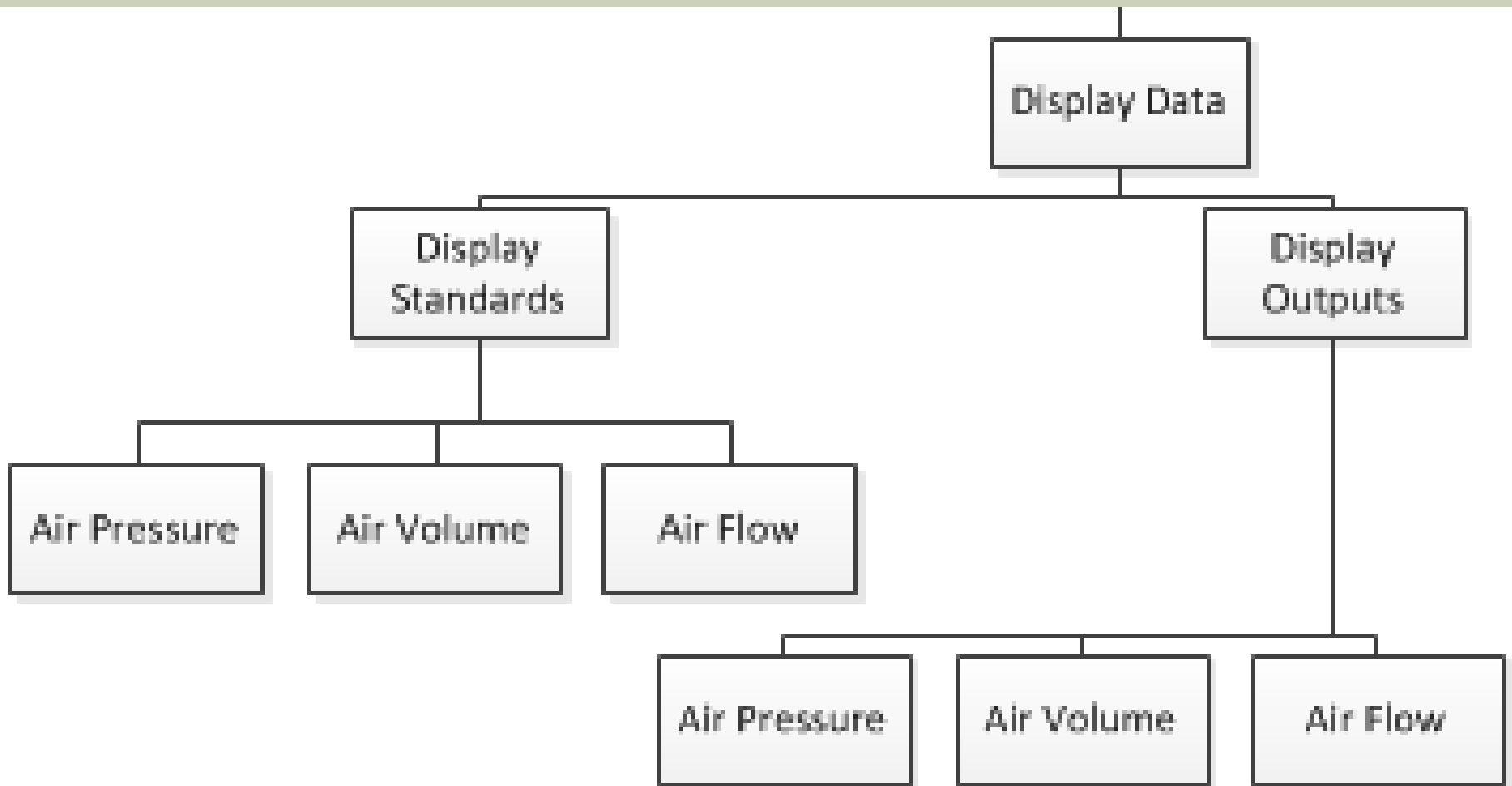
Maintain PEEP  
Level



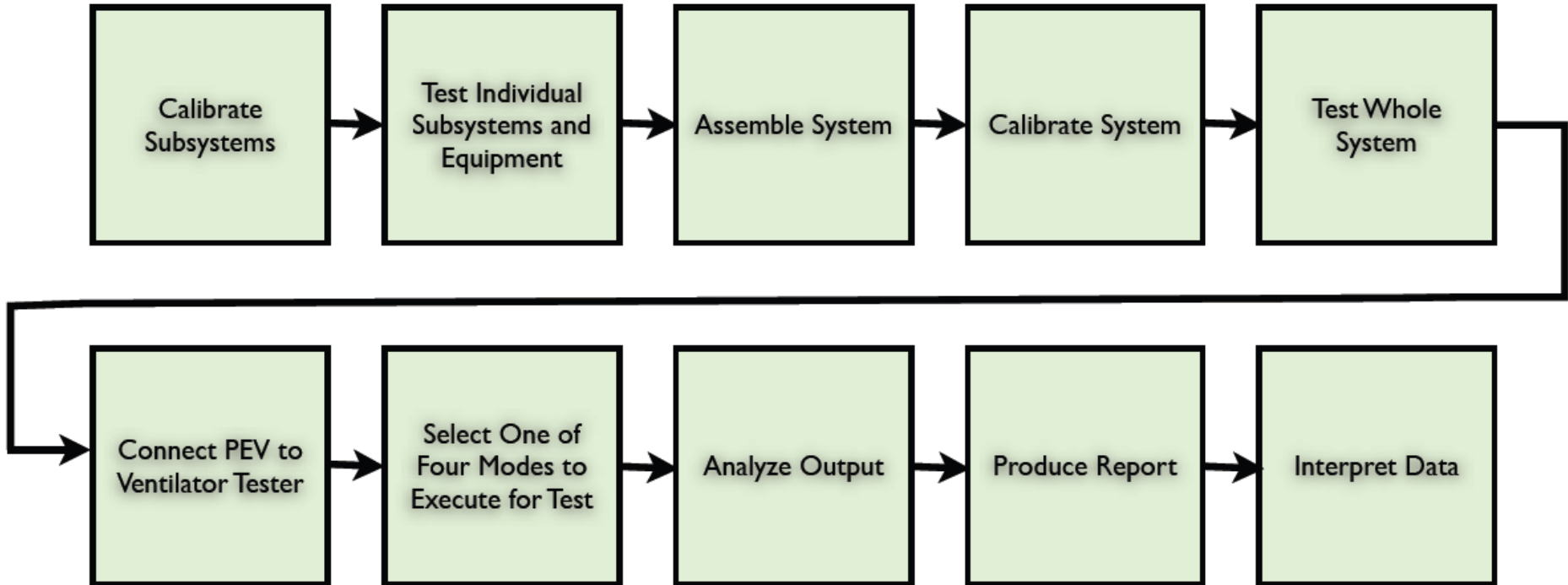
# FUNCTIONAL DECOMPOSITION



























# FUNCTIONAL DECOMPOSITION





# PROCESS PROPOSAL



# CONCEPT GENERATION

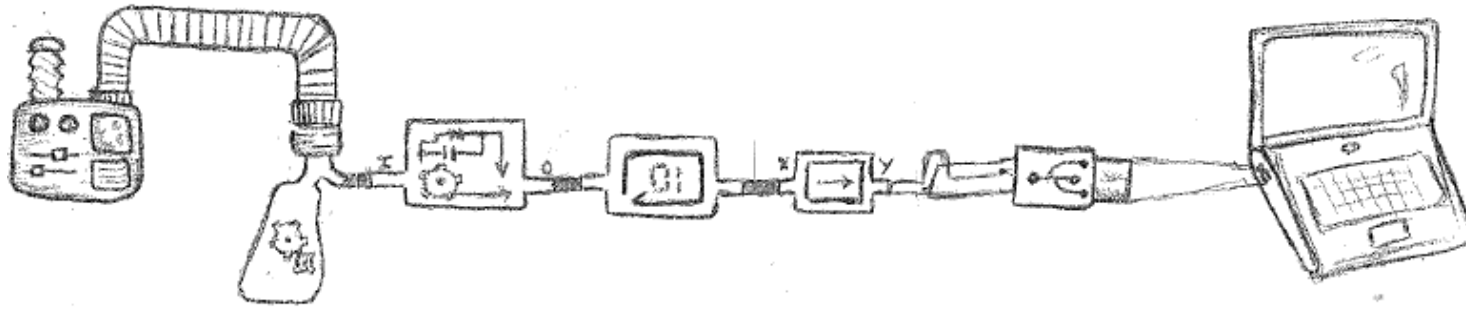
Function	Concept Generation								
Display Data	Interpreter	Write in Notebooks	Word Document	Robot with Laser Pointer	Robot with Verbal Reading of Outputs	Robot with Visual Counter	Poster	Computer Display	
									
Generate Database	Google Docs	MS Access	Unpaid Intern	Hire someone	Apple Cloud	MS Excel	Online Database		
									
Collect Data	Unpaid Intern	Hire Someone	Train a Puppy	LabView	MS Excel	Random Number Generator	MatLab	Pressure gage	Flow sensors
									

# CONCEPT GENERATION

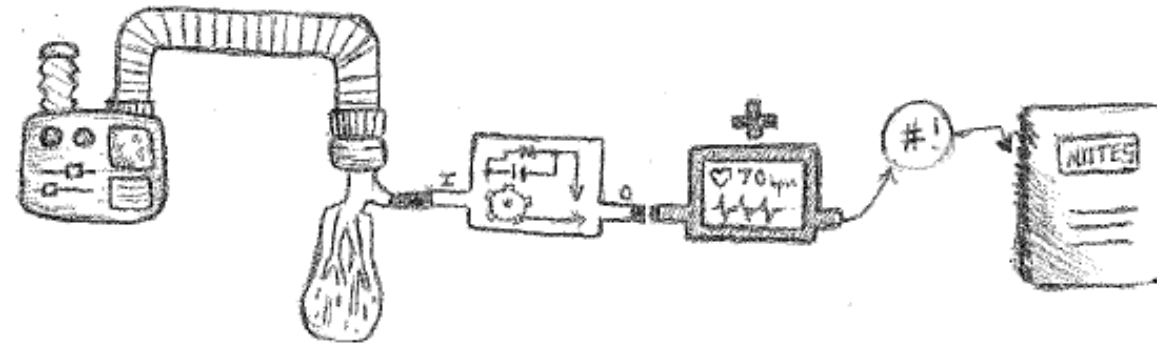
Function	Concept Generation						
Simulate Human Respiratory System	Artificial lung 	Animal lung 	Electromechanical system 	Computerized model 	CPR dummy 	Live person 	MEMs (lung incorporated on chip) 
Interface with the PEV	Electromechanical system 	Mechanical system 	Electrical system 	Human mouth 			
Interpret Input	Computer program 	Human reaction 	Medical personnel 	Medical devices 	Mechanical Device 		
Compare Measures to Standards	Posters 	Computer 	Notebooks 	Graphical Analysis 	Medical devices 		
Display Standards	Posters 	Computer 	Notebooks 	Graphs 	List 		
Display Outputs	Posters 	Computer 	Notebooks 	Graphs 	List 		



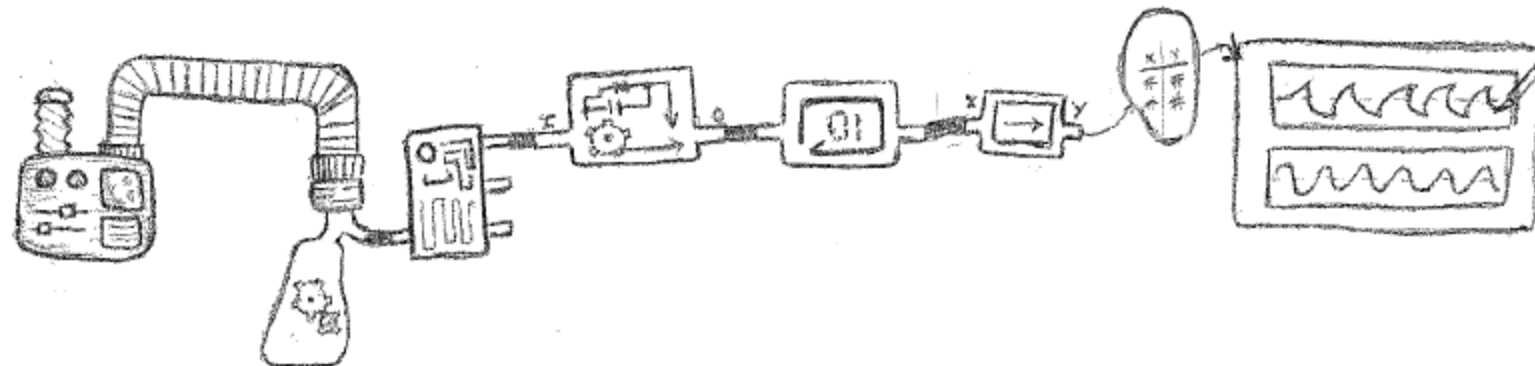
# DESIGN DRAWINGS



Primarily  
Electrical  
System



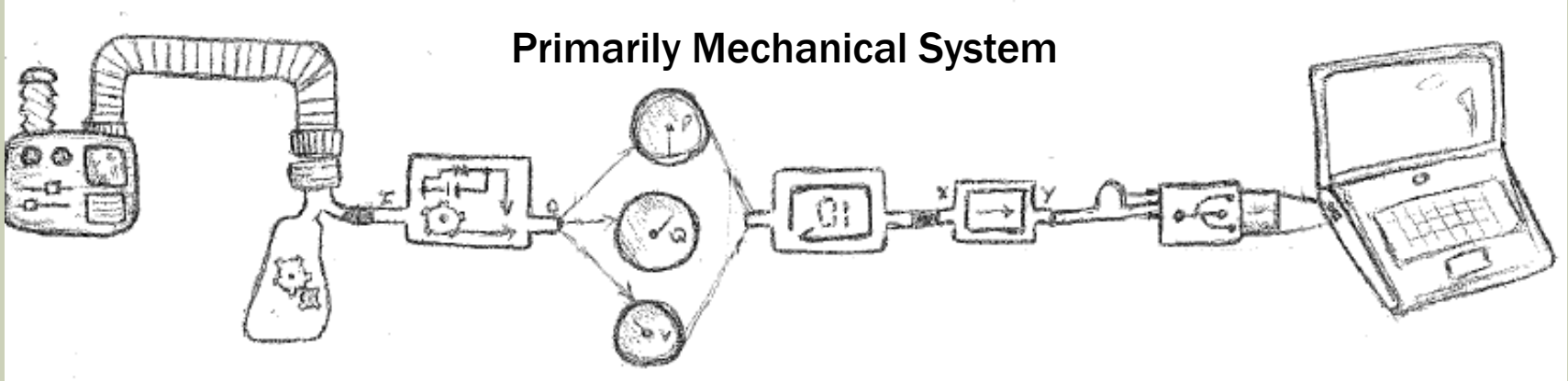
Animal Lung  
System



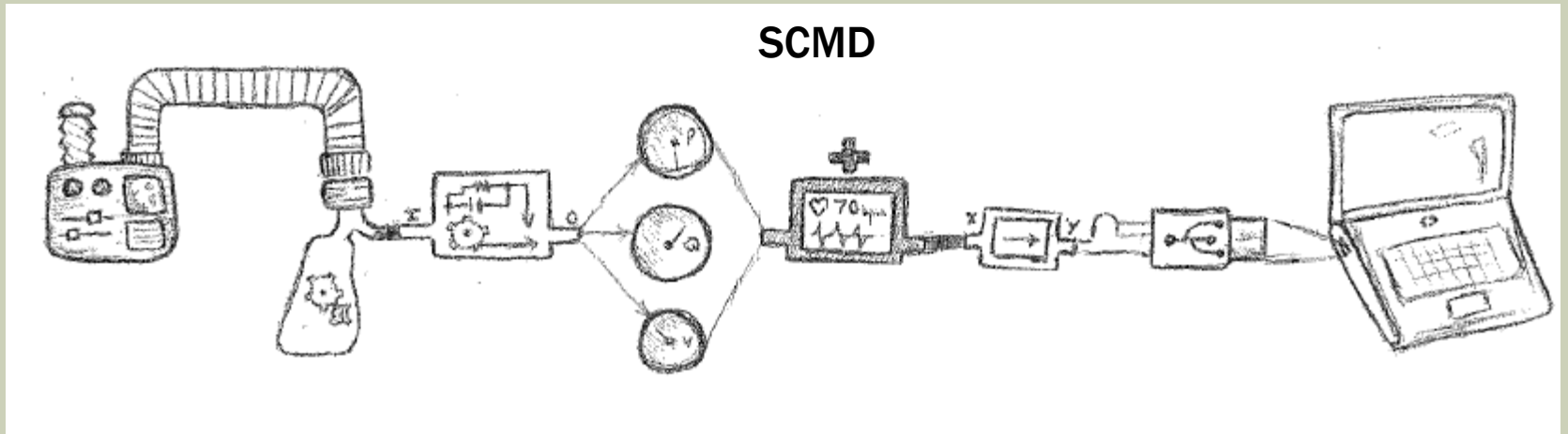
Microprocessor  
System

# DESIGN DRAWINGS (TOP 2)

**Primarily Mechanical System**



**SCMD**



# CONCEPT SELECTION

	A	B	C	D	E	F
	CITREX H4	Primarily Electrical	Primarily Mechanical	Animal Lung System	SCMD	Microprocess or System
<b>Selection Criteria</b>						
<b>Constraints</b>	<b>DATUM</b>					
Can be completed in 2 semesters		+	+	+	+	+
Cost is less than or equal to \$1000		+	+	+	+	+
<b>System Design</b>						
Reliable		-	-	-	S	-
Precision		S	S	-	S	S
Safe		S	S	S	S	S
Accurate		S	S	-	S	S
Repeatable process		S	S	-	-	S
Can test to standards		S	S	S	S	S
Multidisciplinary system		+	+	+	+	-
Resistance to the environment		-	-	-	-	-
Feasibility of the design		-	S	-	S	-
System Appeal		-	-	-	-	-
<b>Sum + 's</b>	<b>0</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>2</b>
<b>Sum 0's</b>	<b>0</b>	<b>5</b>	<b>6</b>	<b>2</b>	<b>6</b>	<b>5</b>
<b>Sum -'s</b>	<b>0</b>	<b>4</b>	<b>3</b>	<b>7</b>	<b>3</b>	<b>5</b>

# CONCEPT SELECTED

	A	B	C	D	E
	SCMD	Primarily Electrical	Primarily Mechanical	Animal Lung System	Microprocess or System
<b>Selection Criteria</b>					
<b>Constraints</b>	<b>DATUM</b>				
Can be completed in 2 semesters		S	S	S	S
Cost is less than or equal to \$1000		S	S	S	-
<b>System Design</b>					
Reliable		-	-	-	-
Precision		S	S	-	S
Safe		S	S	S	S
Accurate		-	-	-	-
Repeatable process		S	S	-	+
Can test to standards		S	S	S	S
Multidisciplinary system		-	-	+	-
Resistance to the environment		-	S	-	+
Feasibility of the design		S	S	-	-
System Appeal		S	S	-	S
<b>Sum + 's</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
<b>Sum 0's</b>	<b>0</b>	<b>8</b>	<b>9</b>	<b>4</b>	<b>5</b>
<b>Sum -'s</b>	<b>0</b>	<b>4</b>	<b>3</b>	<b>7</b>	<b>5</b>

# TEST PLAN

- **Test Mass Flow Sensor**
  - Verify accuracy of the data
- **Test Pressure Sensor**
  - Verify accuracy of the data
- **Test Lung Simulation**
  - Verify lung operations
- **Test Calibration**
  - Verify accuracy of testing system

# RISK ANALYSIS

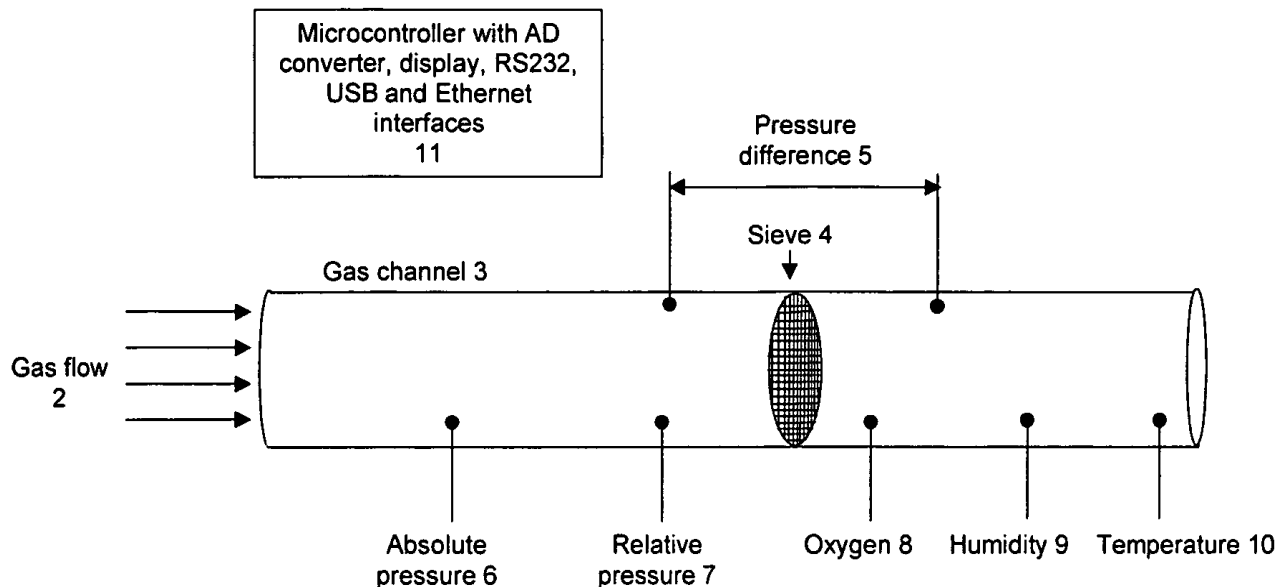
MSD Team 14026 Risk Assessment: Rev. 2

ID	Risk Item	Effect	Cause	Likelihood	Severity	Score	Action to Minimize Risk	Owner
1	Failure to measure outputs accurately.	Potential harm to patient	Poor calibration, damaged sensors, not precise and accurate sensors	2	3	6	Sufficiently understand ability of the sensors	Leslie, Soham, Stephanie
2	Failure of communication between mechanical and electrical systems.	Incorrect output from the system	Not a proper connection between systems, miscommunication	2	3	6	Detailed design reviews with all team members	All
4	Software errors (i.e., compilation error, run time error, inputs do not match the outputs)	Inaccurate output from the system, delay development process, dysfunctional prototype, ineffective testing and poor test results	Human error, programming and calibration errors	3	3	9	Thoroughly comment code for debugging and have useful documentation of software development; quality testing of design	Leslie, Soham, Stephanie, Mike
6	Failure to have a PEV to test	Cannot prove functionality of our system	Potential roadblocks for Mediresp V, current state of Mediresp III and IV is inoperable	2	3	6	Make use of local resources and reach out to hospitals and EMT's that have PEV's available to test	All
12	Not qualified to operate ventilator tester	Damage equipment, inaccurate results, and frustrated customer	No training	2	3	6	Read instruction manual for the testing device and seek assistance from trained medical personnel about training	All
13	Intermittent availability of ventilator tester	Delay schedule of project	Owner has conflicting schedule and is not invested in this project	3	2	6	Reprioritize schedule, leave room for leeway in the event this occurs	All
16	Poor/Ineffective Communication	Progress stalls	Team members are caught up in other priorities, poor guidelines, confusion or discontent with objective	2	3	6	Peer reviews, emails highlighting team's progress, continually ask for clarification	All

# BENCHMARKING

- Gas flow measuring device - US 7212937 B2
  - Imt Medical – FlowAnalyser
  - No tubes between sensors
  - Bidirectional flow measurements are possible
  - Orifice Plate VS Sieve?

Block diagram



# BENCHMARKING

- Simulated human lung for anesthesiology simulation
- **US 5403192 A - Cae-Link Corporation**
  - compact
  - can be controlled to breathe via computer program
  - compliance and resistance can be varied
  - will fit into mannequin's chest cavity

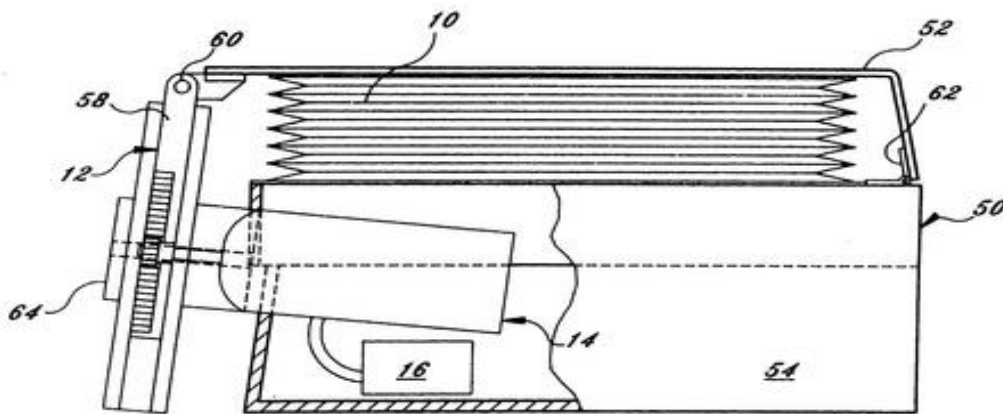


Fig. 2

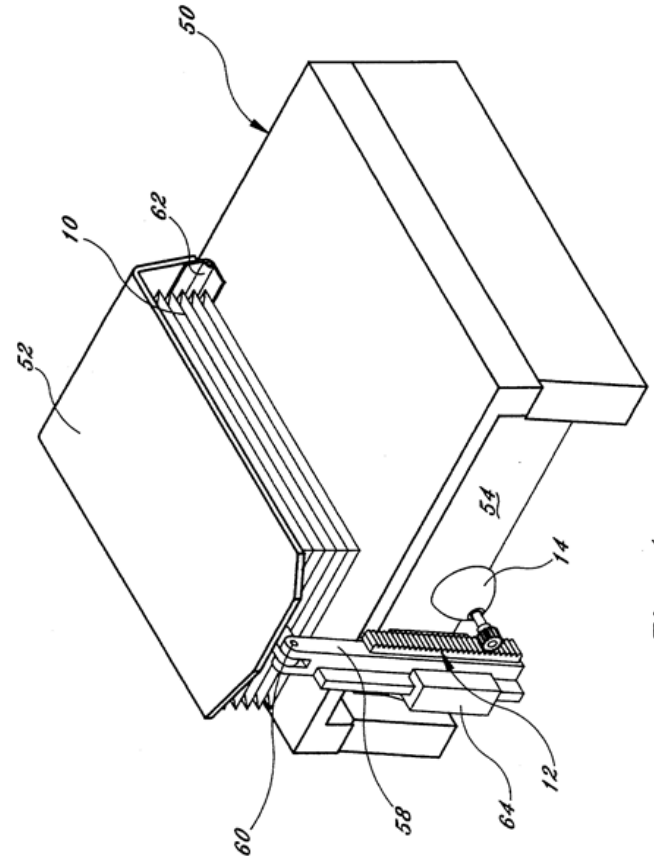


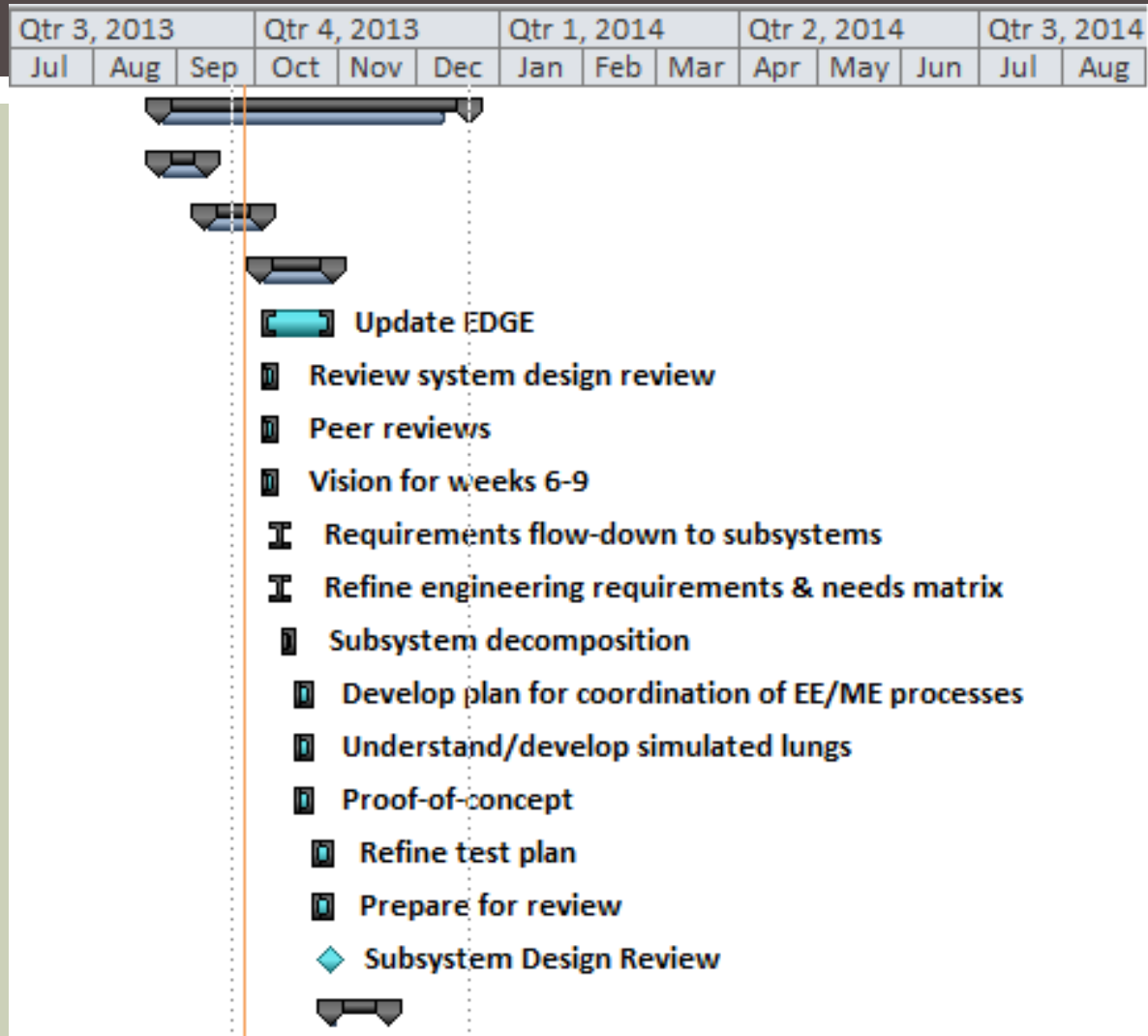
Fig. 4



# BENCHMARKING

- **Other methods of simulating human lungs**
  - **Ventilator test lung and trigger assembly**
    - CA 2699661 A1
    - Uses a rigid container with fixed walls
    - Series of valves control resistance to flow
    - Pneumatic trigger (actuated by vacuum generator) housed inside of rigid container
  - **Servo lung simulator and related control method**
    - WO 1997012351 A1
    - Uses a computer controlled piston to reproduce lung behavior.
    - Volume is measured through piston displacement accurate to 50  $\mu\text{L}$ .
    - Since the model is mathematical and implemented in software, an infinite variety of resistance and compliance values can be chosen by the user.

# SUBSYSTEM SCHEDULE



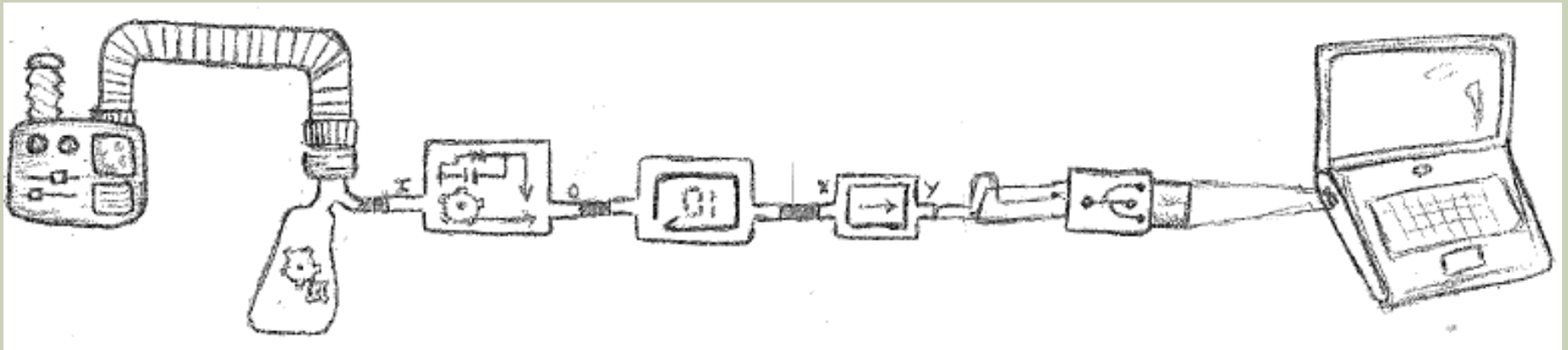
# NEXT STEPS

- Develop contacts at local hospitals
- Discuss peer reviews as a group
- Additional benchmarking of subsystems
  - Functional decomposition of subsystems
  - Concept generation of subsystems
  - Concept selection of subsystems
- Acquire ventilator tester

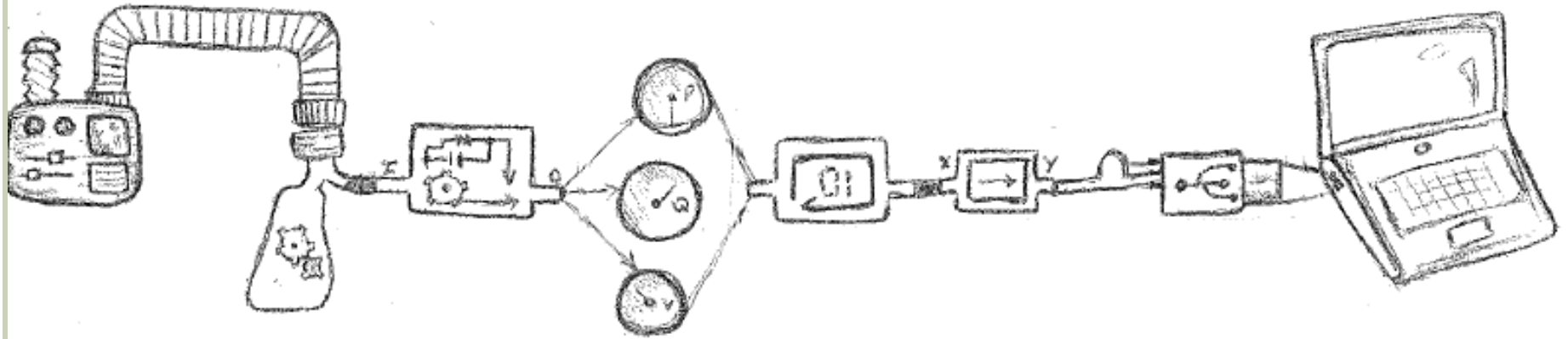
# QUESTIONS



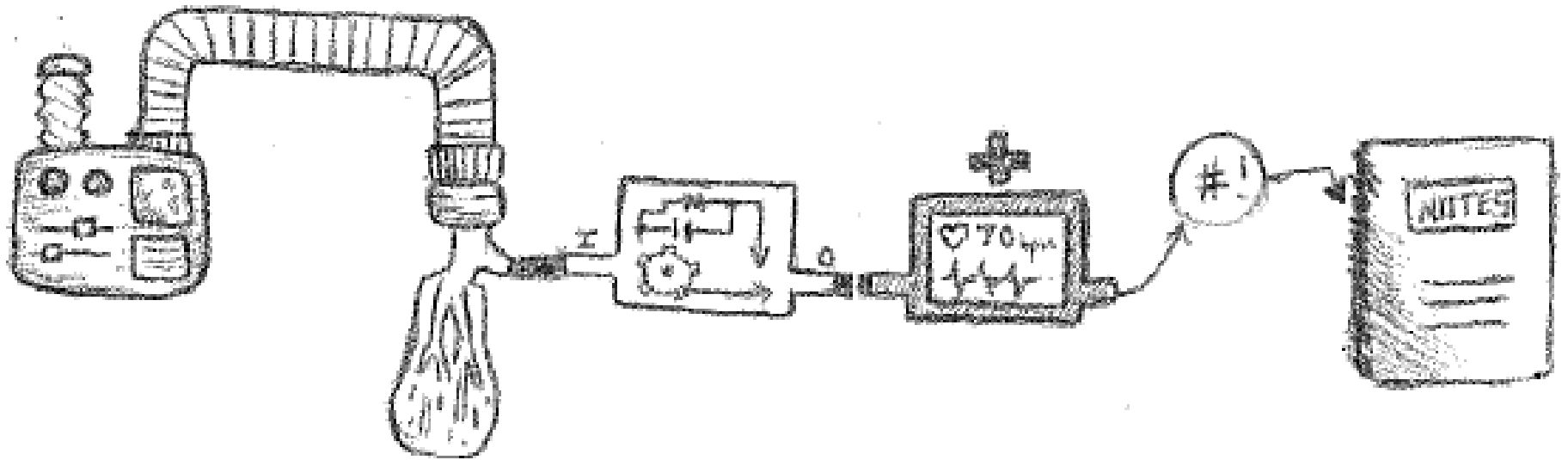
# PRIMARILY ELECTRICAL SYSTEM



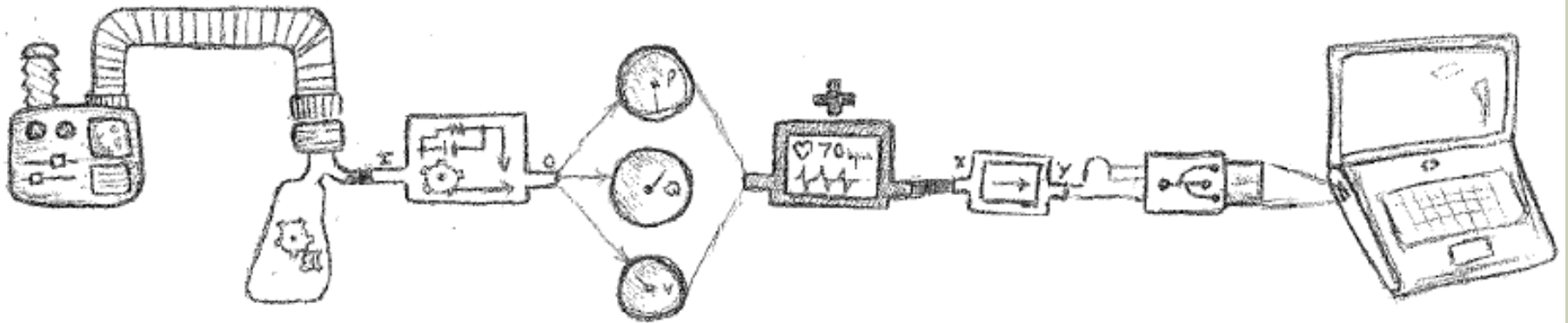
# PRIMARILY MECHANICAL SYSTEM



# ANIMAL LUNG SYSTEM

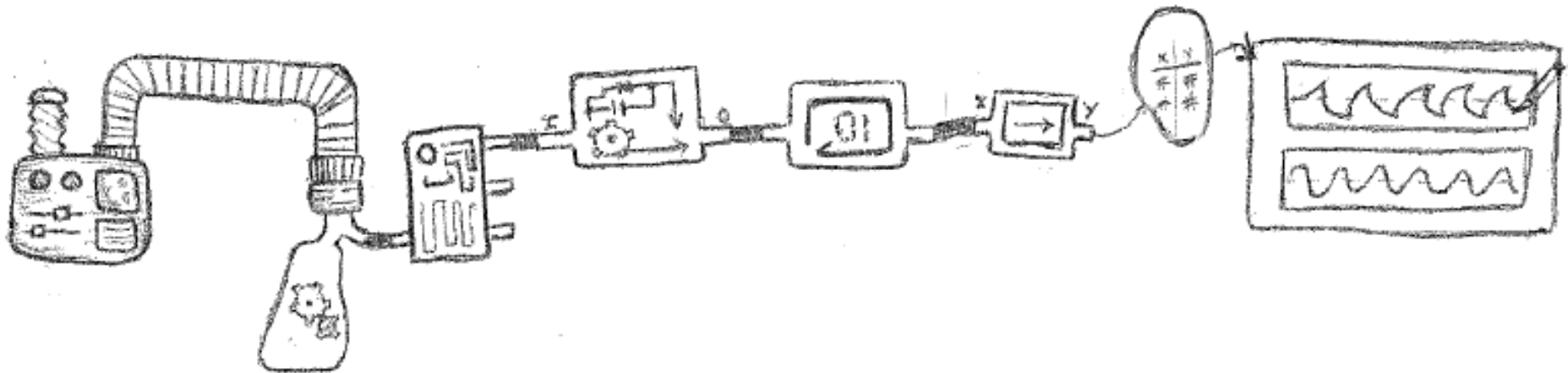


# SCMD (SYSTEM CALIBRATED W/ MEDICAL DEVICE)





# MICROPROCESSOR SYSTEM



# RISK ANALYSIS

ID	Risk Item	Effect	Cause	Likelihood	Severity	Importance	Action to Minimize Risk	Owner
Technical Project Concerns:								
1	Failure to measure outputs accurately.	Potential harm to patient	Poor calibration, damaged sensors, not precise and accurate sensors	2	3	6	Sufficiently understand ability of the sensors	Leslie, Soham, Stephanie
2	Failure of communication between mechanical and electrical systems.	Incorrect output from the system	Not a proper connection between systems, miscommunication	2	3	6	Detailed design reviews with all team members	All
3	Overheating of processor	No output from the system, long delays from input to output	Not sufficient heat removal	1	3	3	Use of proper heat sinks	Leslie, Soham, Stephanie
4	Software errors (i.e., compilation error, run time error, inputs do not match the outputs)	Inaccurate output from the system, delay development process, dysfunctional prototype, ineffective testing and poor test results	Human error, programming and calibration errors	3	3	9	Thoroughly comment code for debugging and have useful documentation of software development; quality testing of design	Leslie, Soham, Stephanie, Mike
5	Failure of seal to maintain or hold air pressure	Inaccurate output from system	Human error, bad insulation, poor connection between parts, bad part	2	1	2	Careful installation of mechanical components; test pressurized air control volume after installation	Andrew, Danielle
6	Failure to have a PEV to test	Cannot prove functionality of our system	Potential roadblocks for Mediresp V, current state of Mediresp III and IV is inoperable	2	3	6	Make use of local resources and reach out to hospitals and EMT's that have PEV's available to test	All

# RISK ANALYSIS

7	Uncalibrated equipment (i.e., power supply is not supplying amount of power it claims to output)	Inaccurate output from system	Poor or overused equipment	2	2	4	Test other values to determine accuracy of equipment; use of DMM to test equipment	All
8	Failure of moving parts/Durability Failure	Inaccurate output of system, equipment failure, component breaking	Wear and tear of parts, improper installation, improper lubrication, component malfunctioning during use	2	2	4	Make sure all moving parts are lubricated and moving correctly; inspect components and connections as they are installed	Andrew, Danielle, Mike
9	Late delivery of parts	Delay schedule of project	Lead time of ordering parts, team doesn't make a decision quick enough	1	3	3	Stay on task, plan ahead, research companies where we are purchasing parts from	Kris
10	Unforeseen losses due to friction	Inaccurate output of system	Human, flawed theoretical model	2	2	4	Check and recheck all calculations, reach out for expertise	Andrew, Danielle, Mike
11	Over-Budget	Working prototype of appropriate vision cannot be created	Necessary parts and technologies are more expensive	2	1	2	Perform cost analysis, benchmarking, utilize current resources on RIT's campus and make informed decisions when purchasing parts	Kris
12	Not qualified to operate ventilator tester	Damage equipment, inaccurate results, and frustrated customer	No training	2	3	6	Read instruction manual for the testing device and seek assistance from trained medical personnel about training	All
Operational Project		Concerns:						
13	Intermittent availability of ventilator tester	Delay schedule of project	Owner has conflicting schedule and is not invested in this project	3	2	6	Reprioritize schedule, leave room for leeway in the event this occurs	All
14	Unable to make use of hospital resources	Unable to satisfy expectations of customer	Hospitals don't have the time or equipment available	3	1	3	Reach out to numerous medical personnel and hospitals; research alternative solutions to satisfy customer needs	All

# RISK ANALYSIS

15	Team skills do not match skills requirement to meet the vision	Poorly distributed workload	Uneven distribution of disciplines	1	3	3	Effective communication	All
16	Poor/Ineffective Communication	Progress stalls	Team members are caught up in other priorities, poor guidelines, confusion or discontent with objective	2	3	6	Peer reviews, emails highlighting team's progress, continually ask for clarification	All
17	Dysfunctional team dynamics	Lack of progress	Not voicing concerns early, different priorities, different values	1	3	3	Peer review as a group, have social time outside project, incorporate fun into work	All
18	Team member leaves in MSD II	Loss of organization, remaining members will need to pick up the extra work, no longer on schedule to complete task	Loss of team member due to injury or co-op	1	3	3	Understanding individual roles within the team and importance to the group and contribution of the project	All

Likelihood scale	Severity scale
1 - This cause is unlikely to happen	1 - The impact on the project is very minor. We will still meet deliverables on time and within budget, but it will cause extra work
2 - This cause could conceivably happen	2 - The impact on the project is noticeable. We will deliver reduced functionality, go over budget, or fail to meet some of our Engineering Specifications.
3 - This cause is very likely to happen	3 - The impact on the project is severe. We will not be able to deliver, or what we deliver will not meet the customer's needs.